



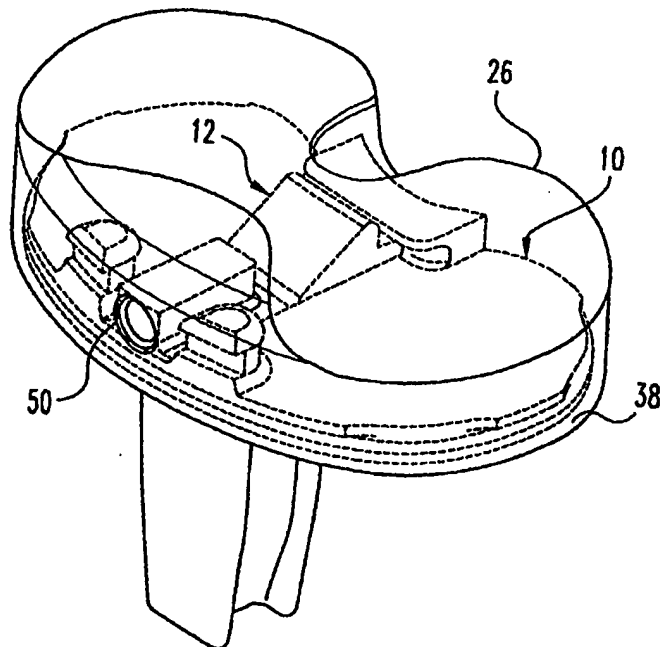
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61F 2/38</b>	<b>A1</b>	(11) International Publication Number: <b>WO 00/23012</b> (43) International Publication Date: 27 April 2000 (27.04.00)
<p>(21) International Application Number: PCT/US99/24235</p> <p>(22) International Filing Date: 14 October 1999 (14.10.99)</p> <p>(30) Priority Data:            09/173,940 16 October 1998 (16.10.98) US            09/174,215 16 October 1998 (16.10.98) US</p> <p>(71) Applicant (for all designated States except US): BIOMET INC. [US/US]; Airport Industrial Park, P.O. Box 587, Warsaw, IN 46581 (US).</p> <p>(72) Inventors; and            (75) Inventors/Applicants (for US only): METZGER, Robert, G. [US/US]; 66847 County Road 3, Wakarusa, IN 46573 (US). ASNIS, Stanley, E. [US/US]; 38 Cornwells Beach Road, Port Washington, NY 11050 (US).</p> <p>(74) Agents: BAHRET, William, F. et al.; Woodard, Emhardt, Naughton, Moriarty &amp; McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).</p>	<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BI, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b>  <i>With international search report.</i></p>	

(54) Title: NONMODULAR JOINT PROSTHESIS CONVERTIBLE IN VIVO TO A MODULAR PROSTHESIS

## (57) Abstract

A nonmodular prosthesis having a retainer for a modular bearing and a nonmodular primary bearing directly molded to the base. A nonmodular tibial prosthesis is provided with a mechanical release member (12) mounted on a tibial base (10) in contact with the nonmodular primary bearing (26). The release member includes a wedge portion (16) with a superiorly posteriorly inclined face, and is designed to be driven anteriorly upon actuation so as to force the primary bearing off of the tibial base, after which the primary bearing and release member are removed and replaced with a modular bearing.



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## NONMODULAR JOINT PROSTHESIS CONVERTIBLE IN VIVO TO A MODULAR PROSTHESIS

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### BACKGROUND OF THE INVENTION

This invention relates to surgically implantable joint prostheses and, more particularly, to a joint prosthesis that combines advantages of modular and nonmodular prostheses.

Artificial joints of the human body, including in particular knee and hip joints, have been available for 50 years or more and have been the subject of intense development for at least the last 20 years. The earliest designs provided metal-to-bone or metal-to-metal contact between the articulating surfaces of a joint. Friction and wear were significantly reduced in subsequent designs by the introduction of ultra-high molecular weight polyethylene (UHMWPE) as a load-bearing surface. For example, a typical knee joint prosthesis has a tibial component with a polyethylene load-bearing surface in contact with a metal femoral component. Early designs of this type had polyethylene cemented to the tibia, but it is conventional today to secure a polyethylene bearing to a metal base or tray which is anchored in the tibia, typically with the aid of a stem or peg extending into the medullary canal of the tibia.

Numerous methods of securing a polyethylene bearing to a metal base have been developed over the years, as exemplified by the following patents:

	Patent No.	Inventor	Issue Date
	4,205,400	Shen et al.	June 3, 1980
	4,217,666	Averill	Aug. 19, 1980
5	4,501,031	McDaniel et al.	Feb. 26, 1985
	4,714,474	Brooks et al.	Dec. 22, 1987
	4,795,468	Hodorek et al.	Jan. 3, 1989
	4,822,362	Walker et al.	Apr. 18, 1989
	4,938,769	Shaw	Jul. 3, 1990
10	4,959,071	Brown et al.	Sep. 25, 1990
	4,963,152	Hofmann et al.	Oct. 16, 1990
	4,997,445	Hodorek	Mar. 5, 1991
	5,061,271	Van Zile	Oct. 29, 1991
	5,080,675	Lawes et al.	Jan. 14, 1992
15	5,108,442	Smith	Apr. 28, 1992
	5,330,534	Herrington et al.	Jul. 19, 1994

There are two general types of components: modular and nonmodular. A  
 20 nonmodular prosthesis has a bearing secured to the base during fabrication in the factory,  
 typically by direct compression molding. A modular prosthesis has a prefabricated  
 bearing designed to be attached to the base during surgery.

A modular prosthesis has several advantages over nonmodular prostheses, one of  
 which is that an assortment of different prostheses, i.e., different base/bearing  
 25 combinations, can be created in the operating room from a small inventory of separate  
 bases and bearings of various sizes, shapes and other characteristics. With a modular  
 prosthesis, an orthopedic surgeon can implant an appropriate base for the patient and then  
 fit the patient with several trial bearings in the process of selecting an appropriate  
 primary bearing to attach to the implanted base. Modular bearings are often readily

removable, and in such cases they have the further advantage of facilitating revision surgery, which may become necessary in cases of traumatic injury or bearing surface wear, by enabling replacement of the bearing without removing the base.

There are also advantages to a nonmodular prosthesis construction, such as design  
5 simplicity due to the absence of a need for a retaining mechanism for a removable bearing, and relatively low cost. An even more significant advantage is that a nonmodular component is virtually immune to micromotion at the interface between the bearing and the base.

Micromotion is very difficult to avoid with modular components due to the need  
10 for clearances between bearing and base to ensure that they fit together during assembly in the operating room. A very secure locking method may avoid the problem, but nonmodular fabrication of the prosthesis, e.g., direct compression molding of a bearing onto a base, avoids the issue. Unfortunately, a nonmodular prosthesis has heretofore made revision surgery more difficult in that the entire prosthetic component must be  
15 removed and replaced. In addition to the extra operating time involved and extraction tools required, such as described in U.S. Patent No. 4,459,985 to McKay, removal and replacement of the base requires sacrificing the existing fixation to the bone and has associated complications, including possible bone loss or fracture and the difficulty of reestablishing solid fixation. Nevertheless, it is conventional wisdom regarding a  
20 nonmodular prosthesis, as stated in the above-referenced Smith patent, that "the bearing component cannot be changed without changing the base component."

## SUMMARY OF THE INVENTION

The present invention combines advantages of modular and nonmodular designs with a nonmodular joint prosthesis that is convertible *in vivo* to a modular device. The prosthesis includes a base having a retainer for a modular bearing, and has a nonmodular primary bearing secured to the base. According to one aspect of the invention relating to a knee joint, the retainer includes a raised portion with a cavity in an inwardly facing surface thereof, and according to another aspect of the invention the retainer is adapted to cooperate with an auxiliary mechanical locking element to securely retain a modular bearing on the base.

A retainer as that term is used herein is a part of the base that is capable, alone or in conjunction with an auxiliary element or elements, of retaining a modular bearing in place on the base. It may be formed on the base as a one-piece or multi-piece retainer.

According to a further aspect of the invention relating to a knee joint, a mechanical release member is mounted on the tibial base in contact with the primary bearing as a part of the nonmodular tibial prosthesis designed to be actuated during revision surgery. Upon actuation, the release member forces the primary bearing off of the tibial base, after which the primary bearing and release member are removed and replaced by a modular bearing. In some cases, conversion to a modular device would be a desirable option even during the primary surgery. It is routine for surgeons to check the patient's range of motion before and after selecting the appropriate size of tibial component and cementing the base to the tibial plateau. With a nonmodular prosthesis the surgeon has little recourse but to dislodge the cemented base and remove it and all the cement from the tibia if the final range-of-motion check is unsatisfactory. The present invention provides a desirable alternative.

A general object of the present invention is to provide an improved surgically implantable joint prosthesis.

Another object of the present invention is to provide advantages of a nonmodular joint prosthesis, including the virtual absence of micromotion, and yet allow a surgeon

performing revision surgery to change to a modular bearing without disturbing the base member and thereby jeopardizing fixation.

Another object of the invention is to extend the lifetime of an artificial joint.

5 These and other objects and advantages of the present invention will be more apparent upon reading the following detailed description of the preferred embodiment in conjunction with the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a tibial base or tray with a release member slidably mounted thereon according to the preferred embodiment of the present invention.

5        FIG. 2 is a perspective view of a complete nonmodular tibial component according to the preferred embodiment of the present invention.

FIG. 3 is a top view of the tibial component of FIG. 2 with one side of the bearing cut away to reveal portions of the base and release member.

FIG. 4 is an anterior view of the tibial component of FIG. 2 with one side of the bearing cut away to reveal portions of the base and release member and with the majority of the stem removed for illustration purposes.

FIG. 5 is a cross-sectional view of the tibial component taken along lines 5-5 in FIG. 4.

FIG. 6 is a side view of an extractor together with a side cross-sectional view of the tibial component of FIG. 2 illustrating the disengagement of the primary bearing from the base upon actuation of the release member with the aid of the extractor.

FIG. 7 is a perspective view of a tibial base or tray with a release member slidably mounted thereon according to a first alternative embodiment of the present invention.

FIG. 8 is an anterior view of the tibial component of FIG. 7 with one side of the primary bearing cut away to reveal portions of the base and release member.

FIG. 9 is a perspective view of a tibial base or tray with a release member slidably mounted thereon according to a second alternative embodiment of the present invention.

FIG. 10 is an anterior view of the tibial component of FIG. 9 with one side of the primary bearing cut away to reveal portions of the base and release member.



## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purpose of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no  
5 limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

10 The preferred embodiment of the present invention will be described with primary reference to a tibial prosthesis for illustration purposes, although the principles of the invention are applicable to other joint prostheses, particularly including artificial hips. With reference to FIG. 1, the preferred embodiment of the present invention as incorporated in a knee joint includes a tibial base or tray 10 and a release member 12  
15 slidably mounted on the intercondylar portion thereof on a smooth, flat superior surface 14. Release member 12 includes a wedge portion 16 and extends between the anterior edge 18 of base 10 and a retaining rail 20 extending superiorly from the posterior edge of the base. Tibial base 10 includes a pair of posts 22 and 24 integrally formed on the superior surface 14 of the base at the anterior edge thereof. As described in further detail  
20 in U.S. Patent No. 5,330,534, which is hereby incorporated by reference, the posts and rail are designed to cooperate to retain a modular bearing on the base, the modular bearing preferably being preformed of ultra-high molecular weight polyethylene (UHMWPE) with anterior and posterior recesses to receive the posts and rail, respectively, and with a uniformly flat inferior surface on its intercondylar and  
25 medial/lateral portions for direct contact with the superior surface 14 of the base. The modular bearing is designed to be locked in position with a transverse slide-in locking bar or clip wedged between the posts and the bearing in opposed grooves provided therein for that purpose. Modular tibial trays and bearings as generally described above are commercially available from Biomet Inc., the assignee of the present invention, as

components of the Maxim® Total Knee System, which includes various sizes and configurations of bases, bearings and stem extensions, as well as femoral and patellar components, for different patient requirements.

According to the present invention, a modular bearing is not implanted as the  
5 primary tibial bearing but instead is secured to the base during revision surgery after *in vivo* removal of a primary bearing which has preferably been molded over the base and the release member. Such a primary bearing 26 is shown in FIG. 2 as part of a complete nonmodular tibial component according to the preferred embodiment of this invention. UHMWPE is also a suitable material for the primary bearing, which is preferably molded  
10 by direct compression molding in a conventional manner.

Release member 12 is preferably formed as a single piece with the thinner, anterior end 28 of wedge 16 integrally joined to an internally threaded drive block 30 and the thicker, posterior end 32 of the wedge integrally joined to a tail 34 which is sized and shaped to partially plug a transverse groove or channel 36 formed in the inwardly facing  
15 surface of rail 20. The wedge suitably has an anterior-posterior length of approximately 0.5", a width of approximately 0.5", and a height of approximately 0.25". The one-piece release member is suitably made of biocompatible titanium machined in a conventional manner, or may be cast cobalt-chromium. Its surfaces are preferably all smooth.

The shape of the release member is shown in greater detail in FIGS. 3-6, from  
20 which it can be appreciated that the molded bearing conforms to the shape of the base and release member, filling all exposed spaces within the mold cavity, which is sized with respect to the base to provide a skirt 38 which covers the peripheral edge of the base and fills an elongated anterior edge groove 40, two medial/lateral edge grooves 42 and two posterior edge grooves 44 in the base as shown in the drawings. The skirt thus  
25 cooperates with other portions of the molded bearing, as will be described, to secure the bearing to the base. To the extent that any polyethylene wear debris may be produced at the bearing-base interface due to micromotion, the skirt also tends to contain such debris. The thickness of the skirt adjacent to each such groove, measured in the plane of the superior surface 14 of the tibial base, is suitably approximately .020-.030". The skirt

thickness in that plane is correspondingly greater at the edge portions 41 and 43 of the base, where the edge of the base is cut away from its superior surface to the superior surface of a ledge 45 which partially defines the grooves. Preferably the inferior edge 46 of the skirt is trimmed after molding such that it is not flush with the interior surface 47 of the base, as will be explained, in order to minimize the chances of contact with bone cement during implantation.

Each peripheral edge groove 44 extends from the posterior end of its respective edge portion 43 to within 0.1" of the adjacent edge of rail 20. The base has no groove in its posterior edge between the medial and lateral edges of rail 20, as perhaps best shown in FIG. 6. The threaded hole 48 in block 30 is a #12-24 hole and is plugged during the molding process by a set screw (not shown) which is later removed and which may, if desired, extend out of the hole virtually to the mold cavity wall to facilitate the creation of an access hole 50 for an extractor, as will be described, in the anterior surface of the bearing. A manual or automatic trimming step is contemplated to clear any residual polyethylene out of the desired hole 50, which is suitably circular but may be square or otherwise shaped. The threaded hole in block 30 may be left unplugged in the tibial component as implanted.

Transverse groove 36 in rail 20 is partially plugged by tail 34 and partially exposed in the mold, as perhaps best illustrated in FIGS. 1 and 5, and it is filled with polyethylene during the molding process to the extent so exposed. Anterior grooves 52 and posterior grooves 54 in posts 22 and 24 are entirely exposed and are thus entirely filled with polyethylene in the preferred embodiment during the molding process. Incidental molding of polyethylene also occurs in the space between the release member and the superior surface of the base at the medial and lateral edges of the inferior surface of the release member, which edges are chamfered to match the radius of curvature of posts 22 and 24 as best illustrated in FIG. 4. The chamfered edges preferably extend the entire length of the release member. The inferior surface of the release member is otherwise smooth and flat. The medial and lateral edges of the superior surface of the wedge at its

posterior end 32 may also be rounded if desired to maintain a particular bearing thickness at such points.

The portions of the molded primary bearing lying in the grooves in the posts and rail, including the portion of groove 36 directly posterior to tail 34 as well as the portions of groove 36 on either side of the tail, cooperate with each other and with the molded bearing portions in peripheral edge grooves 40, 42 and 44 to secure the primary bearing on the tibial base. An example set of groove dimensions suitable for this purpose is set forth below:

	<u>Groove No.</u>	<u>Height</u>	<u>Width</u>	<u>Depth</u>
10	36	.125"	.8"	.1"
	40	.06"	2.2"	.04"
	42	.06"	.4"	.04"
15	44	.06"	.5"	.04"
	52	.125"	.3"	.05"
	54	.1"	.25"	.1"

The dimensions in the above table are most suitable for a tibial base having a nominal size of 71 mm, i.e., a maximum medial/lateral dimension of 71 mm. The peripheral edge groove widths for other base sizes would preferably vary in approximate proportion to base size.

The tibial component with the bearing as shown in FIG. 2 is designed for cases in which the posterior cruciate ligament is retained. Preferably, the same tibial base can accommodate bearings for cruciate-retaining applications and bearings for cruciate-substituting applications, where the tibial component is subjected to higher moments at the implant-bone interface. As is known in the art, the bearing in a cruciate-substituting prosthesis includes a stabilizing post which projects superiorly from the articulating surface level. With the knee loaded in a flexed position, such a stabilizing post

experiences an anteriorly directed force due to the absence of the posterior cruciate ligament. The force creates a moment about the transverse axis through the posts on the base that, if not counteracted, would cause the posterior edge of the bearing to lift off of the base. The base and posterior stabilized bearing must cooperate to withstand the load  
5 that is normally carried by the posterior cruciate ligament, and the tibial base as described above is so designed.

More specifically, the tibial component with the base and release member as described above has a molded bearing retention force, measured in terms of the maximum anteriorly directed force against a posterior stabilized bearing that the tibial  
10 component can sustain without dissociation, in excess of 400 lbs., which is well above the maximum expected *in vivo* load of 320 lbs. This retention force has been measured in a worse-case scenario in which the base is made in the minimum size presently available in the Maxim® product line (59 mm) and the bearing is molded to the base with the maximum rated polyethylene thickness presently available in the Maxim®  
15 product line (24 mm), with no compressive load. The test is performed by connecting a Maxim® femoral component to the tibial component at 90° flexion and then loading the femoral component axially to create an anterior force against the stabilizing post on the tibial bearing. The retention force would be greater with larger base sizes.

Referring now to FIG. 6, the molded primary bearing is removed by actuation of  
20 the release member with the aid of an extractor 60 having a ball screw 62 enmeshed with a recirculating ball nut 64 that is nonrotatably mounted in a casing 66 having an axially extending prong 68 mounted on the distal end thereof on either side of the ball screw as a brace for the extractor. Each prong 68 has a pointed tip, one of which is partially cut away in FIG. 6 to reveal a portion of a threaded nose on a conical adapter, as will be  
25 described below. A suitable ball screw for such purposes is commercially available from Thomson Saginaw Ball Screw Company, Inc., Saginaw, Michigan, as Catalog No. 720426SS. A compatible ball nut is the Thomson Catalog No. 5708278 ball nut. A precision steel ball bushing bearing, Thomson Catalog No. A-81420, is mounted in the proximal end 70 of the casing to rotatably and slidably support an unthreaded proximal

portion 72 of the ball screw shaft, and a T-handle 74 is mounted on that end of the ball screw shaft for rotation and consequent axial motion thereof. The tool preferably includes a releasable ratchet mechanism (not shown) to prevent clockwise rotation of the ball screw, thereby allowing the surgeon's grip on the T-handle to be temporarily released for repositioning during retraction of the ball screw. The ball screw shaft also has an unthreaded distal portion 76 on which is rotatably mounted an adapter 78 having an externally threaded nose 80 designed to engage the threaded drive block 30 of release member 12 in the tibial component. Access hole 50 in the bearing is formed with an inner diameter greater than the outer diameter of nose 80 for this purpose.

In operation, the ball screw is advanced sufficiently to position the nose of the adapter axially beyond the prongs, and the nose of the adapter is then inserted through circular hole 50 in the anterior surface of the bearing and threaded into drive block 30 by manual rotation of the adapter. The ball screw is then retracted with the aid of the T-handle, without rotating the adapter. The prongs indent and thus firmly engage the anterior surface of the bearing as the ball screw is retracted, and, with the spacing between the bearing and ball nut fixed by the prongs, the release member is accordingly pulled anteriorly, whereupon the action of the wedge causes the bearing to move superiorly and disengage from the base. The primary bearing is raised to the point of disengagement and then removed with the release member as a unit, as shown in FIG. 6. With the extractor as described above, the maximum translational force required to be exerted to remove a molded primary bearing from a 71 mm tray is approximately 670 pounds, which corresponds to a torque of approximately 30 inch-pounds applied to the handle end of the ball screw shaft. This amount of torque is well within the capability of a surgeon or surgical assistant of normal strength.

Those skilled in the art will appreciate from FIG. 6 and the foregoing description that the translational force exerted by the extractor is applied between the bearing and the release member, thereby avoiding any disturbance to the base. The bearing is removed substantially in one piece, although fragments of polyethylene may remain on the base, such as in posterior grooves 54 of posts 22 and 24. Any such fragments are easily

removed, and the primary bearing is then replaced with a modular bearing and locking bar of the type described in the above-referenced Patent No. 5,330,534.

Preferably the skirt on the molded primary bearing is trimmed after molding such that its inferior surface is not flush with the inferior surface 47 of the base, and, if  
5 desired, the skirt may be trimmed such that its inferior surface is flush with the superior surface of ledge 45. When the tibial component is implanted, such trimming spaces the bearing apart from the tibial plateau and thus tends to minimize the chances of contact with bone cement, which is often applied to the tibial plateau to help secure the tibial base thereto and which may be present and exposed to some degree adjacent to the  
10 periphery of the base. As a result, the primary bearing can be removed by actuation of the release member, as described above, without significant risk of unwanted resistance from bone cement or of any removal or disturbance of bone cement. As an alternative to such trimming, the mold may be modified, if desired, to provide a correspondingly shorter skirt on the bearing.

15 The modular bearing has no skirt and is no wider than the tibial base, and is therefore slightly smaller than the primary bearing, which extends slightly beyond the peripheral edge of the base as described above and as shown, e.g., in FIGS. 3 and 4. Alternatively, the modular bearing may be made as wide as the primary bearing it is designed to replace, such that it likewise extends slightly beyond the peripheral edge of  
20 the base, albeit without a skirt.

A one-piece construction is preferred for the tibial base. The base may be machined from titanium with an integral stem but is preferably cast of cobalt-chromium. While a stem is a preferred part of the tibial component, the principles of the invention also apply to a stemless tibial base.

25 A first alternative embodiment of a nonmodular tibial component according to the present invention is shown in FIGS. 7 and 8. In this embodiment, a base 110 has an undercut portion 140 which is filled with polyethylene during the molding process and which cooperates with other molded bearing portions as in the preferred embodiment described above to secure the primary bearing on the tibial base. The undercut portion

may extend around the entire periphery of the base or selected portions thereof. The construction of the tibial component, including release member 112, posterior rail 120, anterior posts 122 and 124, and molded primary bearing 126, is otherwise the same as that of the preferred embodiment described above. This embodiment may be useful in certain applications, such as in uncemented tibial implants where there is no possibility of contact with bone cement.

FIG. 9 is a perspective view of a second alternative embodiment of a nonmodular tibial component according to the present invention. In this embodiment the release member 212 is provided with a pair of transverse arms 213 and 214 on the anterior end of the drive block 230. The posterior sides of the transverse arms fill the anterior grooves in posts 222 and 224 provided at the anterior edge of the base 210, and the anterior sides of the transverse arms are provided with respective cutting ridges 215 and 216 each of which extends the length of its arm, as shown in FIG. 9. The cutting ridges are provided to facilitate passage of the anterior end of the release member through the anterior portion of the primary bearing 226 and thereby facilitate forward motion of the release member. A scalpel may be used during revision surgery to cut into or through the relatively thin layer of polyethylene (approximately .010-.020") covering the cutting ridge, if desired, to further facilitate the release action.

In this embodiment, tibial base 210 has a smooth, flat peripheral edge 218 rather than a grooved or undercut edge as in the previous embodiments. Base 210 and the rail 220 and posts 222 and 224 integrally formed thereon are otherwise the same as their counterparts in the preferred embodiment, as is release member 212. Due to the smooth, flat edge and the transverse arms, this embodiment provides less retention force than the previous embodiments, which may be suitable in some circumstances such as in cruciate-retaining applications. The retention force could be increased in this or either prior embodiment by forming the release member without a tail that extends into the channel in the rail. However, in this embodiment the anterior portion of the bearing already tends to disengage from the base well before the posterior portion. It is believed more desirable in most applications to have the anterior and posterior portions of the primary



bearing disengage from the tibial base at approximately the same time, i.e., with negligible tilting, as in the preferred embodiment.

The present invention also encompasses other forms of retainers and other methods of removing a molded primary bearing without removing the base. Other retainer forms  
5 presently contemplated as useful to varying degrees in certain applications include pegs, posts, holes or other recesses, dovetail configurations, tongue and groove configurations, mortise and tenon configurations, retaining walls, rails, detents, and snap ring grooves.

For example, while the intercondylar posts and rail of the preferred embodiment constitute the preferred form of modular bearing retainer according to the present  
10 invention, the retainer may alternatively be in the form of a raised flange or rim about other portions or all of the periphery of the tibial base, with a cavity in an inwardly facing surface of the flange or rim, wherein the modular bearing has a corresponding tongue or lip on its outer edge surface that fits into the cavity, as in Patent No. 4,938,769 to Shaw or Patent No. 4,795,468 to Hodorek et al. Alternatively, or in addition as  
15 disclosed in the latter patent, the modular bearing may be secured to the base with the aid of an auxiliary locking element in the form of a spring clip that interlocks a groove in the rim wall and a corresponding groove in the outer edge surface of the bearing. The clip is mounted in one groove so as to protrude therefrom and snap into the other groove when the modular bearing is pressed against the base. According to the present invention, the  
20 spring clip is preferably not incorporated in the primary tibial prosthesis, and the molded primary bearing preferably extends into the groove in the rim.

As another alternative, the base may be provided with a threaded hole or holes designed to cooperate with a screw or screws to securely retain a modular bearing in place after the molded primary bearing has been removed during revision surgery. Such  
25 screws thereby serve as auxiliary mechanical locking elements. For example, a base with an internally threaded stem designed to retain a modular bearing with the aid of a screw, as disclosed in U.S. Patent No. 4,959,071 to Brown et al., may be modified to have an undercut peripheral edge and then placed in a mold adapted to provide a polyethylene skirt which covers the peripheral edge and extends into the undercut portion sufficiently

to secure the bearing to the base. The threaded stem hole is first plugged with a set screw or otherwise sealed to prevent entry of polyethylene, such as by covering the hole with a stopper of titanium or other suitable material to withstand the heat and pressure in the mold without deformation or fusing to the base.

5       The molded primary bearing in the alternative embodiment just described is preferably removed *in vivo* by selectively cutting the skirt at the peripheral edge and then lifting the main portion of the bearing off of the base, using an osteotome if necessary or desired in conjunction with either a preformed slot or a slot that is cut or melted into the polyethylene at that time at the bearing-base interface to facilitate removal. A witness  
10       mark may be provided on the bearing edge surface at the time of molding to mark the level of the interface for such purposes. The set screw or stopper in the stem hole is removed after the primary bearing, and a modular bearing is then placed on the base and secured with a screw as described in the above-referenced Brown patent, which is hereby incorporated by reference along with the above-referenced patents to Shaw and Hodorek  
15       et al. The removal technique just described may be facilitated by the use of a C-clamp with an osteotome mounted on one end or jaw, with the C-clamp connected across the bearing, e.g., in contact with the medial and lateral edges of the bearing, with the tip of the osteotome inserted into a slot provided for that purpose or aligned with a witness  
20       mark. The opposing forces exerted by the C-clamp do not disturb the tibial base. This technique may also be used in lieu of a release member for removal of a bearing molded to any of the tibial bases of FIGS. 1, 7 or 9.

      Similarly, a pin may be placed through a coaxial pair of through holes in a modular bearing and base and held in position by a clip as described in Patent No. 5,061,271 to Van Zile, which patent is hereby incorporated by reference. The tibial base may have  
25       one or more dovetail surface members such as disclosed in the above-referenced Van Zile or Shaw patents.

      The retainer may alternatively be designed to allow a modular bearing to float to some degree, either by translation or rotation. For example, a modular bearing may be rotatably mounted on a tibial base and retained thereon by means of an unthreaded hole

in the surface of the base in cooperation with a mating stem on the inferior surface of the bearing. Peripheral edge grooves may be provided on the base and filled with polyethylene, as described above with reference to FIG. 1, in order to secure a nonmodular bearing to the base. Similar transversely oriented grooves may be provided at a desired depth within the hole in the base if desired. The nonmodular tibial prosthesis preferably includes a centrally mounted release member having a wedge and drive block similar to that shown in FIG. 1, with the wedge portion wider than the hole in the base.

Also, other forms of release members are contemplated, including one-piece and multi-piece mechanisms. For example, two wedges with complementary inclined surfaces could be provided with a counterdrive mechanism to force the wedges toward or away from each other, depending on their orientation, so as to jointly raise the bearing off of the superior surface of the base.

In another alternative embodiment, the molded primary bearing is adapted to be pulled directly away from the superior surface of the base with the aid of a release member in the form of a simple plate, e.g., a relatively thin disc, located between the bearing and base. A modified form of the extractor shown in FIG. 6 is adapted to engage the plate through an access hole provided in the superior surface of the bearing as molded. The plate has a threaded hole with its axis perpendicular to the superior surface of the base, and is mounted in the intercondylar area of the base in place of the release member shown in FIG. 1. A #12-24 hole is suitable as in the preferred embodiment. A through hole coaxial with the hole in the plate is provided in the superior surface of the bearing as an access hole for a threaded nose of an extractor as shown in FIG. 6 but modified to have a longer nose for this purpose. The extractor is adapted to be aligned with the access hole axis with a fixed spacing between the extractor casing and the tibial base. This spacing may be maintained with prongs as shown in FIG. 6 but spaced further apart so as to straddle the bearing and engage contact points provided on the base for this purpose. The contact points may, for example, be peripheral extensions of ledge 45 on the base of FIG. 1 which are not covered with polyethylene during the molding process. If the prongs have pointed tips as in the embodiment of FIG. 6, each contact point on the

base preferably has an indentation in its superior surface to receive a prong tip and fix its position in the transverse plane. The base is otherwise the same as shown in FIG. 1.

In operation, the extractor is positioned with the prongs on the contact points on the base and the extended nose of the extractor threaded into the plate. The ball screw of the extractor is then retracted, whereby the plate exerts a superiorly directed force against the bearing and thus raises it off of the base surface. For this purpose, the shear area of the portion of the molded bearing above the plate is greater than the total shear area of the portions of the molded bearing in the grooves in the posts, rail and peripheral edges of the base.

As an alternative to prongs of the type shown in FIG. 6, the extractor may be provided with a pair of jaws with opposed sharp edges adapted to cut into the peripheral skirt on the bearing and engage the medial/lateral edge grooves 42 in the tibial base, whereby the extractor may be clamped to the base. With the nose of the extractor threaded into the plate, the primary bearing may be pulled directly away from the superior surface of the base along with the release plate upon retraction of the ball screw in the extractor.

Alternatively, the primary bearing may be removed *in vivo* by sectioning, reaming or grinding the bearing or key points thereof. As one example of such a technique in the context of a hip joint prosthesis, an acetabular cup having a porous shell may be provided with an annular groove for retention of a preformed bearing insert as a modular revision bearing, and the primary bearing may be formed in the porous shell by direct compression molding of polyethylene which is later reamed out during revision surgery sufficiently to allow insertion of the preformed insert. The shell may be either a metal shell with a porous coating or an uncoated shell made of a porous material having structural integrity such as porous tantalum. An acetabular cup with an interior annular groove, in a nonporous metal shell, is disclosed in U.S. Patent No. 5,571,201 to Averill et al., which patent is hereby incorporated by reference. That groove is designed to receive cement, but, alternatively, a similar groove may be designed and constructed to receive a snap ring for mechanical retention of a bearing insert provided with a corresponding

groove for the snap ring. The groove in the cup is preferably masked off prior to the molding process with a removable annular plug of a material that will not fuse to the polyethylene or shell during the molding process. During revision surgery, a surgeon would ream the primary bearing down to the surface of the porous shell, remove the  
5 annular plug, and then insert a modular bearing insert.

A bearing of the type shown in FIG. 2 but molded to the base 10 without a release member thereon may alternatively be removed by sectioning. For example, a medial-lateral strip 1/4" to 1/2" wide may be cut out of the bearing with a saw or mill, and the remaining anterior and posterior bearing portions may then be forced toward each other,  
10 and thereby disengaged from the posts, the rail and the edge grooves on the base, with the aid of pliers or a clamp adapted with prongs or otherwise to pierce or otherwise firmly engage the anterior and posterior bearing surfaces.

Reamers, saws and osteotomes may disturb a prosthesis or damage it, e.g., by scratching the smooth superior surface of a tibial base. Therefore, while methods  
15 involving such tools are options for revision procedures, it is preferred to incorporate a release member in the nonmodular prosthesis which allows a bearing to be removed without the application of force to the base member.

It is also contemplated that the nonmodular bearing may be secured in ways other than by molding in certain applications. For example, an interference fit may be  
20 provided between a preformed bearing and a mating base with the aid of a press in the factory. Thermally aided assembly is another alternative. For example, a barbed central post on the base may be heated so as to locally melt the polyethylene in a preformed bearing as the bearing is pressed onto it; upon cooling, the polyethylene is secured to the post and thereby to the base, which may be provided with ancillary retaining elements  
25 such as a retaining rim. A nonmodular prosthesis may also be fabricated using a permanent adhesive to secure a preformed bearing to a base. Such methods are considered possible although not preferred. A recess must be provided in the bearing's inferior surface for a release member if one is desired for the intended application.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the  
5 invention are desired to be protected.

What is claimed:

1. A nonmodular tibial prosthesis convertible *in vivo* to a modular device, comprising a tibial base having a modular bearing retainer on its superior surface, said  
5 retainer including a raised portion with a cavity in an inwardly facing surface thereof, and a nonmodular primary bearing secured to said tibial base.
2. The prosthesis of claim 1, wherein said raised portion is at the posterior edge of said tibial base.
- 10 3. The prosthesis of claim 2, further comprising means for removing said nonmodular primary bearing from said tibial base substantially in one piece without disturbing said tibial base.
- 15 4. The prosthesis of claim 3, wherein said removing means includes a wedge, and wherein said primary bearing is directly molded over said wedge.
5. The prosthesis of claim 4, wherein said tibial base includes a flat intercondylar superior surface, wherein said wedge includes a flat inferior surface in  
20 contact with said flat superior surface of said tibial base, and wherein said wedge includes a posteriorly superiorly inclined superior surface in contact with a correspondingly inclined inferior surface of said primary bearing.

6. The prosthesis of claim 5, further comprising a threaded drive block integrally joined to the anterior end of said wedge.

7. The prosthesis of claim 1, further comprising a wedge mounted on said  
5 tibial base, wherein said primary bearing is directly molded over said wedge.

8. The prosthesis of claim 1, further comprising a plurality of said raised portions with a cavity in an inwardly facing surface thereof, wherein said plurality of raised portions includes a plurality of posts at the anterior edge of said tibial base and a  
10 rail at the posterior edge of said tibial base.

9. A nonmodular tibial prosthesis convertible *in vivo* to a modular device, comprising a tibial base having a modular bearing retainer adapted to cooperate with an auxiliary mechanical locking element to securely retain a modular bearing on said tibial  
15 base, and a nonmodular primary bearing secured to said tibial base.

10. The prosthesis of claim 9, wherein said retainer includes a raised portion with a cavity in an anterior-facing surface thereof at the posterior edge of said tibial base.

20 11. The prosthesis of claim 9, wherein said retainer further includes a pair of posts at the anterior edge of said tibial base, and wherein said auxiliary mechanical locking element comprises a clip adapted to engage said posts and the modular bearing.

12. The prosthesis of claim 9, wherein said retainer includes a threaded hole,  
25 and wherein said auxiliary mechanical locking member comprises a screw.

13. The prosthesis of claim 9, wherein said retainer includes a dovetail surface member.



14. The prosthesis of claim 9, further comprising means for removing said nonmodular primary bearing from said tibial base substantially in one piece without disturbing said tibial base.

5        15. A nonmodular tibial prosthesis convertible *in vivo* to a modular device, comprising:  
a tibial base having a surface defining a retainer for a modular bearing;  
a nonmodular primary bearing secured to said tibial base; and  
a mechanical release member mounted on said tibial base in contact with said  
10 nonmodular primary bearing.

16. The prosthesis of claim 15, wherein said release member includes a wedge, and wherein said primary bearing is directly molded over said wedge.

15        17. The prosthesis of claim 16, wherein said tibial base includes a flat intercondylar superior surface, wherein said wedge includes a flat inferior surface in contact with said flat superior surface of said tibial base, and wherein said wedge includes a posteriorly superiorly inclined superior surface in contact with a correspondingly inclined inferior surface of said primary bearing.

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18. The prosthesis of claim 17, further comprising a threaded drive block integrally joined to the anterior end of said wedge.

19. A nonmodular tibial prosthesis convertible *in vivo* to a modular device,  
25 comprising:  
a tibial base having means for retaining a modular bearing thereon;  
a nonmodular primary bearing secured to said tibial base; and  
release means for releasing said nonmodular primary bearing from said tibial base without disturbing said tibial base.

20. The prosthesis of claim 19, wherein said release means includes a wedge, and wherein said primary bearing is directly molded over said wedge.

5        21. The prosthesis of claim 20, wherein said tibial base includes a flat intercondylar superior surface, wherein said wedge includes a flat inferior surface in contact with said flat superior surface of said tibial base, and wherein said wedge includes a posteriorly superiorly inclined superior surface in contact with a correspondingly inclined inferior surface of said primary bearing.

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22. The prosthesis of claim 21, further comprising a threaded drive block integrally joined to the anterior end of said wedge.

23. A method of replacing a knee joint, comprising:  
15        providing a tibial base with a retainer for a modular replacement bearing to be secured to said tibial base after removal of a primary bearing therefrom;  
          securing a nonmodular primary bearing to said tibial base; and  
          implanting said tibial base with said retainer and nonmodular primary bearing in a patient during primary knee replacement surgery.

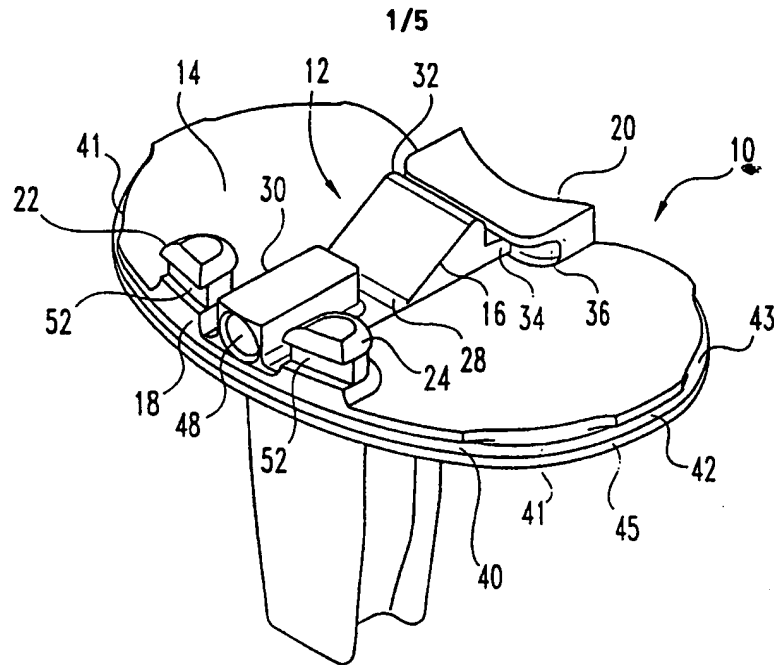
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24. The method of claim 23, further comprising:  
          removing said nonmodular primary bearing during revision surgery without removing said tibial base; and  
          securing a modular bearing to said retainer during said revision surgery.

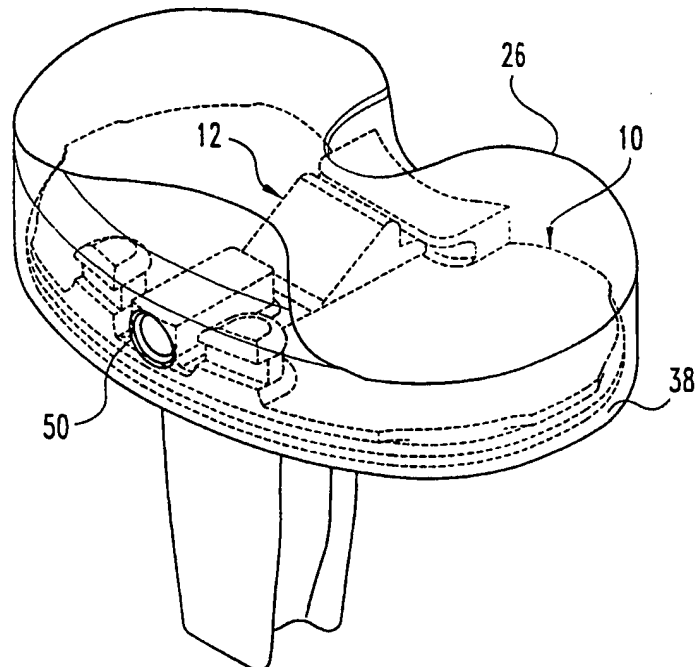
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25. A nonmodular tibial prosthesis convertible *in vivo* to a modular device, comprising a tibial base having a hollow stem portion adapted to rotatably support a modular bearing, and a nonmodular primary bearing secured to said tibial base.

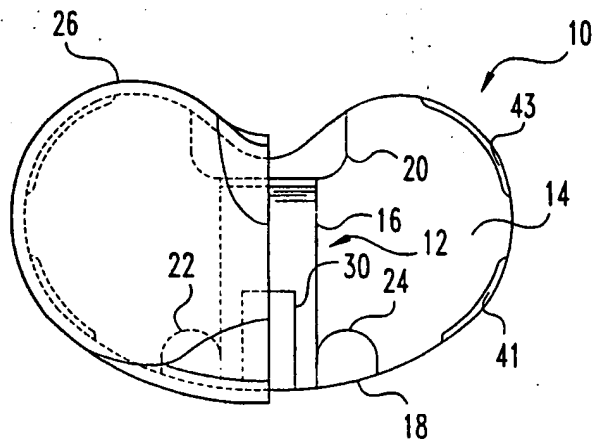
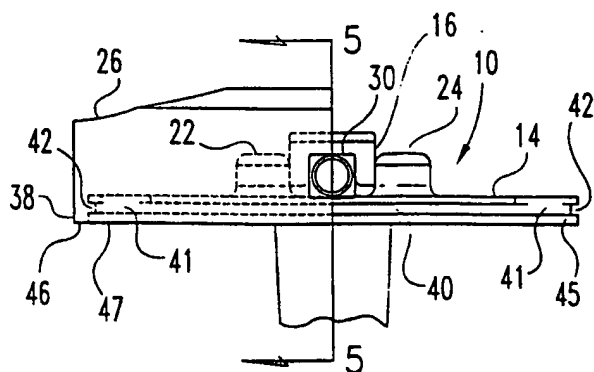
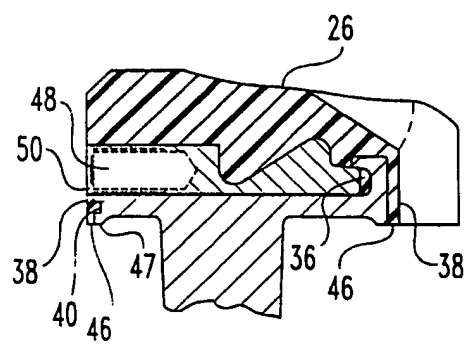
26. A nonmodular joint prosthesis convertible *in vivo* to a modular device, comprising a base having a modular bearing retainer, and a nonmodular primary bearing directly molded to said base.



**Fig. 1**



**Fig. 2**

**Fig. 3****Fig. 4****Fig. 5**

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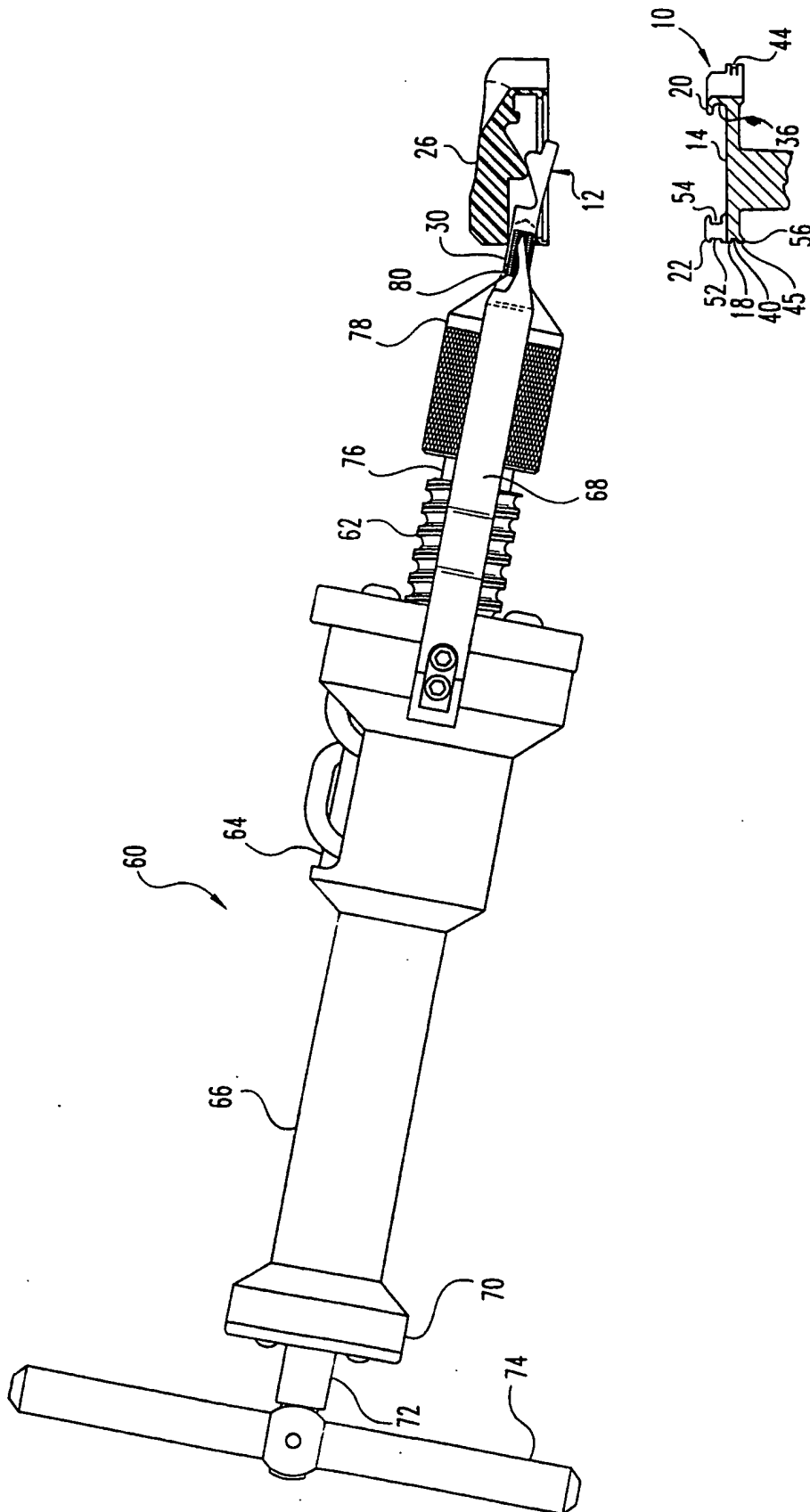
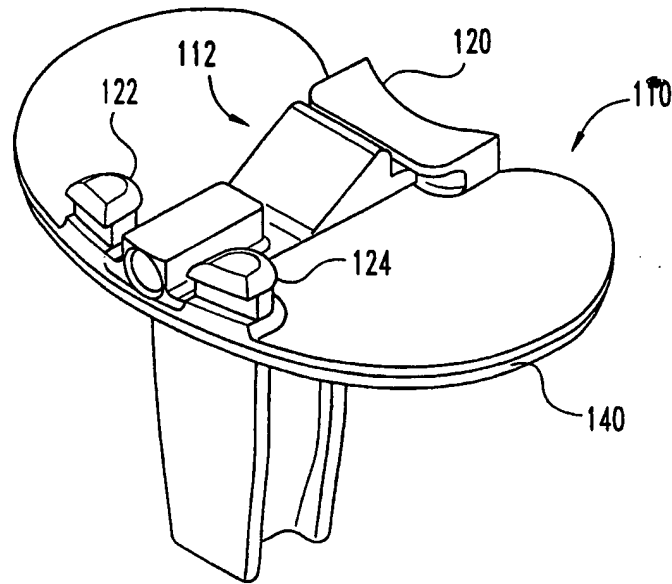
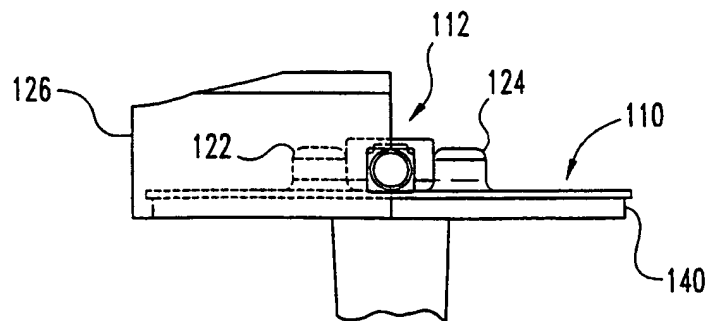
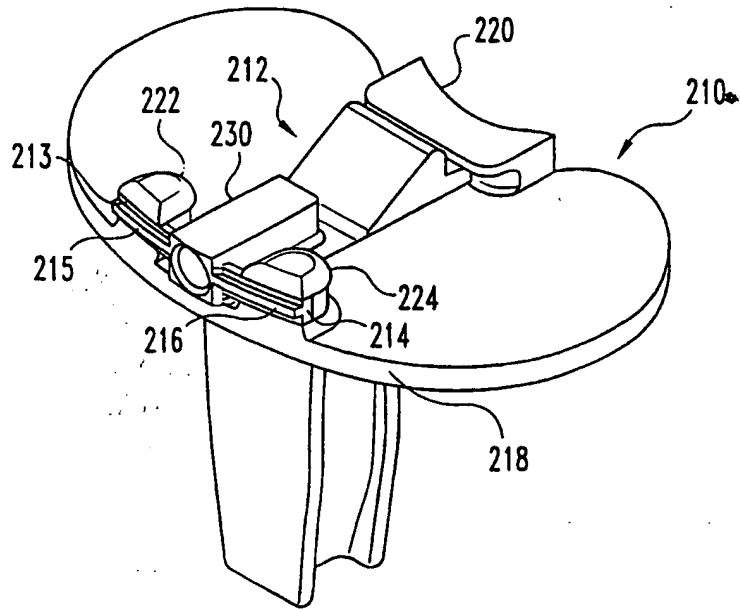
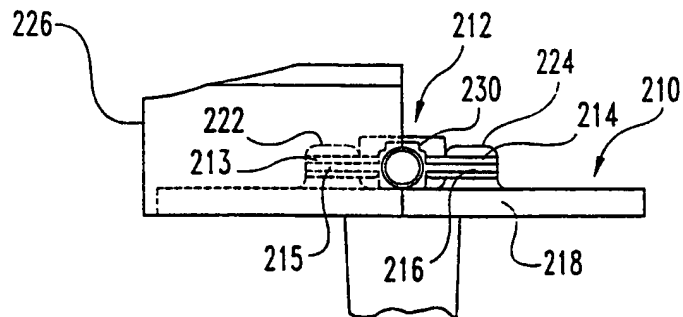


Fig. 6

**Fig. 7****Fig. 8**



**Fig. 9**



**Fig. 10**



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT-US99/24235

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(6) :A61F 2/38 US CL :623/20 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) U.S. : 623/18, 20  Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EAST. WEST Search Terms: tibial prosthesis, bearing, detach\$		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,330,534 A (HERRINGTON et al.) 19 July 1994, col. 6 lines 39-44, 62-65, col. 7 lines 4-35, especially Figs. 2 and 4.	9-11, 14-16, 19, 25, 26
X,P	US 5,824,103 A (WILLIAMS) 20 October 1998, col. 5 lines 10-19, 34-39; col. 6 lines 18, especially Figs. 1, 5, 6 and 17.	9, 12-14, 19, 20, 23-26
X	FR 2 702 651 A (GERARD et al.) 23 September 1994, Abstract, and Fig. 1.	9-11, 13-15, 19, 20, 25, 26
Y, P	US 5,928,286 A (ASHBY et al.) 27 July 1999, col. 3 lines 5-11, 29-37; col. 6 lines 43-47, especially Figs. 2, 4, 11 and 19.	1-3, 9, 10, 12, 14, 15, 19, 25, 26
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* "A" "E" "L" "O" "P"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance earlier document published on or after the international filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed	"T" "X" "Y" "&" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art document member of the same patent family
Date of the actual completion of the international search 28 DECEMBER 1999		Date of mailing of the international search report 03 FEB 2000
Name and mailing address of the ISA-US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer BRIAN PELLEGRINO Telephone No. (703) 306-5899